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EXAMINER	
FETTEROLF, BRANDON J	

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1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,323	WU ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 13-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to the Amendment

The Amendment filed on 7/10/2007 in response to the previous Non-Final Office Action (1/05/2007) is acknowledged and has been entered.

Claims 1-4, 6 and 13-16 are currently pending and under consideration.

Rejections Withdrawn:

The rejection of claims 1, 2 and 13 under 35 U.S.C. 112, second paragraph, because it is unclear whether Applicants are attempting to claim a composition or a method is withdrawn in view of Applicants submission that the instant claims encompass composition claims (page 5 of Remarks).

Rejections Maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 remains rejected under 35 U.S.C. 112, second paragraph, because it is unclear which elements are excluded from the transitional phrase "consisting essentially of" in claim 13. There is no clear definition provided in the specification for ingredients or steps that would materially affect the composition or the method. See *PPG*, 156 F.3d at 1355, 48 USPQ 2d at 1355 for example. Therefore, the "consisting essentially of" language in the claim is being interpreted as "comprising", see the MPEP § 2111.03.

In response to the rejection, Applicants assert that the term "consisting essentially of" used preceding a list of ingredients means that the composition includes the listed ingredients and is open to unlisted ingredients that do not materially affect basic and novel properties of the invention. PPG Indus. V. Gaurdian Indus. Corp., 156 F.3d 1351, 1353, 48 USPQ2d 1351, 1353-4 (Fed. Cir. 1998). Applicants further assert that to determine the ingredients included versus excluded from the

claims by this language, one must read the claims in light of the specification (Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. 1989)); and that there is no requirement that the specification include an express teaching of what is included and excluded by the "consisting essentially of" language. As such, Applicants assert that one skilled in the art at the time of the invention upon reading the specification would readily understand that the two ingredients listed after the term "consisting essentially of" are the active ingredients that achieve the claimed inhibiting development and metastasis of the claimed method. Moreover, Applicants contend that one skill in the art would understand that the claims would not encompass compositions that include ingredients, other than the two listed ingredients that materially effect the development and metastasis of the listed cancers and carcinomas.

These arguments have been carefully considered, but are not found persuasive.

First, the Examiner acknowledges and agrees with Applicants assertions with respect to the term "consisting essentially of"; and further, that there is no requirement that the specification include an express teaching of what is included or excluded by the phrase "consisting essentially of" language. Moreover, the Examiner acknowledges and agrees with Applicants that one of skill in the art would readily understand that the two ingredients listed after the term "consisting essentially of" are the active ingredients that achieve the claimed inhibiting development and metastasis of the claimed properties. However, the Examiner recognizes that there is no general teaching in the specification that would differentiate what is considered to be materially altering to the skilled artisan. In other words, the specification does not appear to set forth what other ingredients would alter the properties of inhibiting development of and metastasis of the recited cancers. Thus, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Claim 13 recites a composition for inhibiting carcinogenesis and metastasis of colon cancer, lung carcinoma or mammary adenocarcinoma in a subject, comprising administering a composition consisting essentially of a therapeutically effective amount of an Astragalus radix and Codonopsis pilosulae radix mixed extract, wherein the weight ratio of Astagalus radix:Codonopsis pilosulae radix in the mixed extract is from 3:1 to 1:3. However, there is no written support for excluding any elements from the claimed method in the disclosure. Applicant has also not pointed to any disclosure that teaches which elements would alter the basic and novel characteristics of the invention. Therefore, it remains unclear what is to be materially excluded that would alter the invention. There is no teaching in the specification that would differentiate what is considered to be materially altering to the skilled artisan. The Office is not requiring a list of specific materials that would have to be excluded from the claimed method, but a general teaching of properties that would effect the invention. It is applicant's burden to teach what would materially alter the characteristics of the claimed invention. See *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964) and *Ex Parte Hoffman*, 12 USPQ2d 1061, 1063-64. With this type of teaching, the skilled artisan would be able to readily discern what would be excluded from the "consisting essentially of" claim language. However, since there is no general teaching of this kind in the specification, the claim remains rejected because it introduces new matter into the disclosure.

In response to this rejection, Applicants assert that, as discussed above for rejection of claim 13 under 112, 2nd paragraph, the boundaries of the claims preceded by the term "consisting essentially of" are dictated by considering the claims in light of the specification, wherein the specification sufficiently apprises one skilled in the art what the novel properties of the invention are and what compounds are included in the claims that affect those novel properties. In particular, Applicants assert that the novel property of the invention is directed to a method for treating specific cancers using a specific dose of a composition including two active ingredients. Thus, Applicants assert that one of ordinary skill in the art would understand from the specification and claims that adding an ingredient to the dosed composition that impacts the "inhibiting development and metastasis of" the recited cancers would fall outside the scope of the claims.

These arguments have been carefully considered, but are not found persuasive.

As stated above, the Examiner acknowledges and agrees with Applicants assertions with respect to the term "consisting essentially of"; and further, that there is no requirement that the specification include an express teaching of what is included or excluded by the phrase "consisting essentially of" language. However, the Examiner recognizes that while one skilled in the art would recognize in light of the specification that the claimed composition includes Astragalus radix and Codonopsis pilosulae radix, the specification does not appear to set forth what other ingredients would alter the properties of inhibiting development of and metastasis of the recited cancers. In other words, there is no general teaching in the specification that would differentiate what is considered to be materially altering to the skilled artisan.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6 and 13 **remain** rejected and **new** claim 14 is under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 2004/0105902, 2004, *of record*).

Chen et al. teach a composition for treating prostate cancer comprising a therapeutically effective amount of *Astragali radix* (referred to also as Huang Qi) and *Codonopsis pilosulae radix* (page 2, paragraph 0017). With regards to the composition, the publication teaches that the composition consists of weight ratio of 1:1 (page 4, 2nd column, Example 1). Chen et al. further teach that the composition may be in the form of a solution and/or tablet/capsule (page 3, 1st column, paragraph 0026). Moreover, Chen et al. teach that the average dosage for an animal is about 20 to about 90 grams (paragraph 0027). Although Chen et al. do not specifically teach that the purified *Astragali radix* and *Codonopsis pilosulae radix* are extracted from a particular species, the claims are drawn to a composition comprising the two specific extracts, e.g., *Astragali radix* and *Codonopsis pilosulae radix*. Thus, the claimed composition appears to be the same as the prior art. The office does not have the

facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Along the same lines, while Chen et al. do not specifically teach that the composition can be used for the treatment of colon cancer, lung carcinoma or mammary carcinoma, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

In response to this rejection, Applicants contend that the amended claims are drawn to compositions for inhibiting certain kinds of cancers, e.g., colon cancer, lung carcinoma or mammary carcinoma. As such, Applicants assert that the instant claims are novel over Chen et al. because, as acknowledged by the Examiner in the last Office Action, Chen et al. does not teach treating these specific tumors. Moreover, Applicants assert that the claimed dosing range is also believed to cause the pending claims to be novel over Chen et al. as well.

These arguments have been carefully considered, but are not found persuasive.

As noted above, the Examiner recognizes that the Chen et al. does not specifically teach that the composition can be used for the treatment of colon cancer, lung carcinoma or mammary carcinoma. However, the Examiner recognizes that the intended use of the compound or in the instant case a composition must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982). Regarding Applicants assertions with respect to the instantly claimed dose, the Examiner points Applicants attention to paragraph 0027 of Chen et al. which teaches that the average dosage for an animal is about 20 to about 90 grams (paragraph 0027). As such, the claimed dose no less than 0.2 g/kg is anticipated by Chen et al.. Applicants are reminded that for the purposes of

searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."

New Rejections Necessitated by Amendment and/or upon Reconsideration:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6 and 13-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for inhibiting metastasis and/or inhibiting tumor growth, does not reasonably provide enablement for a composition for inhibiting the development of colon cancer, lung carcinoma or mammary adenocarcinoma in a subject, comprising administering a composition comprising a therapeutically effective amount of an Astragalus radix and Codonopsis pilosulae radix mixed extract. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the nature of the invention, (2) the relative skill of those in the art, (3) the breadth of the claims, (4) the amount or direction or guidance

presented, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the state of the prior art, and (8) the predictability or unpredictability of the art.

Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406) Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

The nature of the invention

The claims are drawn to a composition for inhibiting development and metastasis of colon cancer, lung cancer, or mammary adenocarcinoma in a subject, comprising administering a composition comprising a therapeutically effective amount of an Astragalus radix and Codonopsis pilosulae radix mixed extract. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Level of skill in the art

The level of skill in the art is deemed to be high, generally that of a PhD or MD.

The breadth of the claims

Applicants broadly claim a composition for inhibiting the development and metastasis of colon cancer, lung cancer, or mammary adenocarcinoma in a subject, comprising administering a composition comprising a therapeutically effective amount of an Astragalus radix and Codonopsis pilosulae radix mixed extract. Thus, the claims encompass preventing cancer, e.g., development of cancer.

Guidance in the specification and Working Examples

The specification teaches that the present invention mainly provides a composition for inhibiting development and metastases comprising administering a therapeutically effective amount of a Astragalus radix and Codonopsis pilosulae radix mixed extract. For example, the specification teaches the effects of different composition comprising a Astragalus radix and Codonopsis pilosulae radix mixed extract on treating metastasis (beginning on page 20, Example 7). Thus, while the specification provides several examples of treating metastasis and inhibition of tumor growth, the specification appears to be silent on a correlation between the claimed composition and inhibiting development, e.g., preventing cancer. As such, if there is no correlation then the examples do not constitute working examples. While it is understood that the absence of working examples should never be the sole reason for rejecting a claims as being broader than an enabling disclosure, the criticality of working examples in an unpredictable art, such as the prevention of cancer, is required for practice of the claimed invention.

Quantity of experimentation

The quantity of experimentation in the areas of cancer therapy is extremely large given the unpredictability associated with treating cancer in general and the lack of correlation of in vitro findings to in vivo success, and the fact that no known cure or preventive regimen is currently available for cancer.

The unpredictability of the art and the state of the prior art

The state of the art at the time of filing was such that one of skill could recognize that composition comprising Astragalus radix and Codonopsis pilosulae radix mixed extracts have been

used for the treatment of cancer. For example, Kexin et al. (of record) teach the clinical effects of Shenqi Fuzheng in treating gastric cancer (abstract). With regards to Shenqi Fuzheng, the reference teaches that Shenqi Fuzheng consists of Huang Qi (astragalus root) and Dang Shen (pilose asiabell root) (page 2 of translation, *Treatment Method*) and is produced as a solution for injection. Along the same lines, Chen et al. (of record) teach a composition for treating prostate cancer comprising a therapeutically effective amount of *Astragali radix* (referred to also as Huang Qi) and *Codonopsis pilosulae radix* (page 2, paragraph 0017). Thus, while these two prior art references are directed to treating various cancer, those of skill in the art recognize that the prevention of cancer is highly unpredictable. The majority of studies suggest that the essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in *advance* of clinical cancer and *link* those results with subsequent histological confirmation of the presence or absence of disease. Further, such studies require the appropriate experimental models for analyzing chemo- or immunoprevention. For example, Granziero *et al.* (Eur. J. Immunol. 1999, 29:1127-1138, *of record*) teach that many models are not suitable for testing immunotherapeutic approaches intended to cure cancer. They suggest that the optimal model (prostate cancer, in their case) would have spontaneous tumor development in its natural location (1st column, page 1128) wherein disease progression would closely resemble the progression of the particular type of cancer. Hence, depending on the type of model employed one could establish a reasonable link between antecedent drug and subsequent knowledge of the prevention of the disease. Further, reasonable guidance with respect to correlating agents that prevent cancer may depend upon quantitative analysis from defined populations that have been successfully pre-screened and are predisposed to particular types of cancer. This type of data might be derived from widespread genetic analysis, cancer clusters, or family histories. For example, Byers, T. (CA Journal, Vol. 49, No. 6, Nov/Dec. 1999, *of record*) teaches that randomized controlled trials are commonly regarded as the definitive study for proving causality (1st col., p.358), and that in controlled trials the random assignment of subjects to the intervention eliminates the problems of dietary recalls and controls the effects of both known and unknown confounding factors. Further, Byers suggests that chemo-preventitive trials be designed "long-term" such that testing occurs over many years (2nd col., p. 359).

Conclusion

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as written.

(Note: In order to expedite prosecution, the Examiner would like to respond to Applicants arguments pertaining to the previous rejection.)

In response to the previous rejection, Applicants assert that the previous rejection has been overcome by amending the claims to methods for "inhibiting development and metastasis of [three listed cancers]". As such, Applicants assert that the claims are commensurate in scope with the specification description and examples and requires little or no additional experimentation on part of persons skilled in the art to practice the invention.

These arguments have been carefully considered, but are not found persuasive.

In the instant case, the Examiner acknowledges and appreciates Applicants for amending the claims to recite inhibiting development and metastasis of [three listed cancers]. However, the Examiner recognizes that there does not appear to be a difference with respect to the issues involved in inhibiting carcinogenesis and inhibiting the development of the three specific types of cancers as they both appear to be drawn to a form of preventing cancer development. As such, the rejection is maintained, but has been formatted to include the amended terminology.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kexin et al. (Chinese Journal of Combined Traditional and Modern Medicine 1999; 19: 11-13, translated, *of record*).

Kexin et al. teach the clinical effects of Shenqi Fuzheng in treating gastric cancer (abstract). With regards to Shenqi Fuzheng, the reference teaches that Shenqi Fuzheng consists of Huang Qi (astragalus root) and Dang Shen (pilose asiabell root) (page 2 of translation, *Treatment Method*) and is produced as a solution for injection. Thus, while Kexin et al. do not explicitly teach that *Codonopsis piola* and the species thereof is also referred to DangShen, it does not appear that the claim language or limitation results in a manipulative difference as compared to the prior art disclosure because the specification discloses (page 1, lines 11-13 and page 4, lines 3-5) that *Codonopsis pilosulae* is also known as Dangshen which is the dried root of *Codonopsis pilola* (Franch.) Nannf, *Codonopsis tangshen* Oliv.. or *Codonopsis pilola* (Franch.) var. modesta (Nannf.) L.T. Moreover, although Kexin et al. do not explicitly teach that *Astragalus radix* and species thereof is also referred to Huang Qi, it does not appear that the claim language or limitation results in a manipulative difference as compared to the prior art disclosure because the specification discloses (page 1, lines 10-11 and 17-20) that *Astragalus radix* is also known as Huang Qi which is the dried root of *Astragalus mogholicus or Astragalus membranaceus*. In addition, although Kexin et al. do not specifically teach that Shenqi Fuzheng can be used for the treatment of colon cancer, lung carcinoma or mammary carcinoma, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982). Lastly, while Kexin et al. do not explicitly teach that the weight ratio of the two components of Shenqi Fuzheng is from 3:1 to 1:3, the office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of

evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Kexin et al. do not explicitly teach that the dose of Shenqi Fuzheng is no less than 0.2 g/kg.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose of Shenqi Fuzheng as taught by Kexin et al. so that it is no less than 0.2 g/kg. One would have been motivated to do so because the Courts have found that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, one of ordinary skill in the art would have a reasonable expectation of success that by optimizing the dose of Shenqi Fuzheng as taught by Kexin et al. through routine experimentation so that the dose is no less than 2 g/kg, one would achieve an effect dose for the treatment of cancer.

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

Therefore, NO claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

BF